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10/509,139	09/27/2004	Reddy Bandi Parthasaradhi	H1089/20010	1949

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EXAMINER	
CHANG, CELIA C	

ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
10/16/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary	Application No.	Applicant(s)	
	10/509,139	PARTHASARADHI ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/18/05, 6/15/05, 11-9/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The finality of the office action dated Jan. 17, 2008 is hereby withdrawn in view of the following new grounds of rejection.

Claims 1-16 are pending.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,943,590 (recited on 1449).

See col. 6, lines 66-68, col. 10, claims 1 and 3.

Please note that the instant claims and the prior art disclosure different in the measurements of crystallinity by powdered X-ray diffraction. Please note that the innate nature of a product, such as the X-ray diffraction pattern does not demarcate from a product which although was not measured by X-ray but are made by the same identical process of crystallization from acetone as the original claims and the specification.

It is well recognized in the art that X-ray diffraction pattern although useful must be carefully evaluated (See US Pharmcopia). Small difference in X-ray lines does not necessarily imply new forms. In addition, it is well known that powder X-ray pattern are unreliable without factual evidence in comparative measurements that artifacts are not at issue (see Davidovich et al.) and the same crystal when taken in powdered process can provide misleading pattern (see Berstein p. 118) while same X-ray pattern can be different compounds. Such degree of understanding offered the scientific basis that powdered X-ray diffraction pattern alone absent of complete multiple character of a product which was made by identical process does not demarcate from the prior art. Thus, anticipation was found.

Applicants deleted the solvent "acetone" from the process claims and alleged that the product as claimed now is not made from acetone see p.4 specification examples 1-2, 5. This is

misleading. Please note that a product made by a process is still a product. Absent of side-by-side comparison, there is no evidence that mere deletion of the solvent acetone from the claim has actually produced a "different" product. In addition, please note that every single evidence in obtaining form I in the specification (see examples 1, 2, 5) is from acetone. Even if, applicants deleted acetone from the process claims, such deletion does not obviate the anticipation since applicants' product was produced by identical process as the prior art.

3. Claims 1-2 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 3-4, and 6-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

"The standard for determining whether the specification meets the enablement requirement [in accordance with the statute] was cast in the Supreme Court decision of *Mineral Separation v. Hyde,* 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also *United States v. Telectronics, Inc.,* 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.").

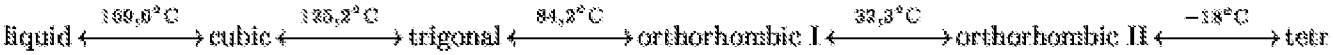
Based on the level of skill as stated in the state of the art reference *Kirk-Othmer Encyclopedia of Chemical Technology* Copyright © 2002 by John Wiley & Sons, Inc., pp. 95-147, Article Online Posting Date: August 16, 2002, the amount of guidance in the specification, the disclosure does not contain sufficient information to enable one skilled in the pertinent art for recovery of such a product as claimed.

Specifically, the amount of guidance or direction needed to enable an invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling. In the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles. Most often, additional factors, such as the teachings in pertinent references, will be available to substantiate any doubts that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof."

In the instant case, the state of the art of polymorph recovery is highly unpredictable. See for example *Kirk-Othmer Encyclopedia of Chemical Technology* Copyright © 2002 by John Wiley & Sons, Inc., pp. 95-147, Article Online Posting Date: August 16, 2002. This article indicates that many uncertain factors determine morphology, and specifically that the appearance of the crystalline product and its processing characteristics (such as washing and filtration) are affected by crystal habit (i.e., the general shape of a crystal). Relative growth rates of the faces of a crystal determine its shape. Faster growing faces become smaller than slower growing faces

and, in the extreme case, may disappear from the crystal altogether. Growth rates depend on the presence of impurities, rates of cooling, temperature, solvent, mixing, and supersaturation. Furthermore, the importance of each of these factors may vary from one crystal face to another, see page 114.

The reference also teaches that polymorphism is a condition wherein crystalline form is intimately associated with processing ("*Polymorphism* is a condition in which chemically identical substances may crystallize into different forms. Each form is, however, only stable (thermodynamically) in a certain range of temperature and pressure. In the case of ambient pressure, eg, ammonium nitrate exhibits four changes in form between -18 and 125°C:



Transitions from one polymorphic form to another may be accompanied by changes in process conditions (temperature, pressure, shear or solution composition), transitions from one polymorphic form to another and lead to formation of a solid product with unacceptable properties (eg, melting point or dissolution rate).

If the product made by using ethylacetate, methyl tert-butyl ether and acetonitrile is *different* from the product made using acetone as exemplified in examples 1, 2 or 5, then, such product must be supported by side-by-side comparison with the prior art product made by acetone. In the instant case, the product being claimed by the process with acetone and without acetone as now amended, was declared by oath to be "identical". Every exemplification wherein form I was obtained employed acetone (see examples 1, 2, 5). No where in the specification provided description or enablement as to what is the product being made by using ethylacetate, methyl tert-butyl ether and acetonitrile.

The instant specification, however, provided no description or enablement that the instantly amended process would produce form I as described by examples 1, 2 or 5 which used exclusively acetone. Therefore, claims 1-2 would be considered to contain *new matter* since a product which is different from those made in acetone was not disclosed.

If such product made by using ethylacetate, methyl tert-butyl ether and acetonitrile is *identical* to the prior art product or made from acetone, then, the prima facie obviousness of

employing different but operable solvent is self evidenced in supporting the rejection of claims 1-16 under 35 USC 103(a) which will be following.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 8-9, and 16 rejected under 35 U.S.C. 102(e) as being anticipated by US 6,916,941.

See col. 5-6, examples 1-2.

Please note that the instant claims and the prior art disclosure different in the measurements of crystallinity by powdered X-ray diffraction. Please note that the innate nature of a product, such as the X-ray diffraction pattern does not demarcate from a product which although was not measured by X-ray but are made by the same identical process of crystallization from acetone as the claims.

It is well recognized in the art that X-ray diffraction pattern although useful must be carefully evaluated (See US Pharmcopia). Small difference in X-ray lines does not necessarily imply new forms. In addition, it is well known that powder X-ray pattern are unreliable without factual evidence in comparative measurements that artifacts are not at issue (see Davidovich et al.) and the same crystal when taken in powdered process can provide misleading pattern (see Berstein p. 118) while same X-ray pattern can be different compounds. Such degree of

understanding offered the scientific basis that powdered X-ray diffraction pattern alone absent of complete multiple character of a product which was made by identical process does not demarcate from the prior art. Thus, anticipation was found.

A product cannot be separated from its innate nature such as the physical properties of the product i.e. x-ray diffraction pattern. Please note that the product as claimed which was described by the specification to be made by any alcoholic solvent. Therefore, the mere deletion of ethanol from the process of making does not obviate the anticipation. If the product which is made by methanol or isopropyl alcohol is a different product from the one made by ethanol, only a side-by-side comparison of the instant product with the prior art product can support such an allegation. If factual evidence showing that a product made by using ethanol is *different* from using methanol or isopropanol, claims 8-9 would be considered to contain *new matter* since a product which is different from those made in ethanol was not disclosed.

5. Claims 8-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 10-11, 13-14, 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The same rational as clearly delineated in section 3 is also applicable to form II made by ethanol solvent and hereby incorporated by reference and therefore:

If the product made by using methanol or isopropanol is *different* from the product made using ethanol as exemplified in examples 3-4 p.5, then, such product must be supported by side-by-side comparison with the prior art product or product made in ethanol. In the instant case, the product being claimed by the process with ethanol and without ethanol as now amended, was declared by oath to be "identical". No where in the specification provided description or

enablement as to a different product being made by using metnaol or isopropanol from the one made using ethanol.

If such product made by using methanol or isopropanol is *identical* to the prior art product or made from ethanol, then, the prima facie obviousness of employing different but operable solvent is self evidenced in supporting the rejection of claims 1-16 under 35 USC 103(a) which will be following.

6. Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

If the form I made by using ethylacetate, methyl tert-butyl ether and acetonitrile is different from the product made using acetone which is supported by side-by-side comparison with the prior art product made by acetone, then, such product and process are new matter which lacks description, because the specification declares under oath that the same identical product was made.

If the form II made by using methanol or isopropanol is different from the product made using ethanol which if supported by side-by-side comparison with the prior art product made by ethanol, then, such product and process are new matter which lacks description, because the specification declares under oath that the same identical product was made with ethanol, methanol or isopropanol.

7. Claims 15-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270

(1916), where the Supreme Court looked to whether the experimentation needed to practice an invention was undue or unreasonable. *Id.* An invention must be described so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). As stated in the MPEP 2164.01(a) "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". The analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. *Id.* at 740, *Id.* at 1407. The factors to be considered herein are those set forth as the In re Wands, 8 USPQ 2nd 1400 (1988) decision.

The analysis is applied to the instant case.

Nature of invention

The claims are drawn to "stable" pharmaceutical composition of crystalline product. Keeping products in its crystalline nature in a pharmaceutical composition is highly unpredictable and empirical.

The state of the art and predictability

The state of the art supported by per ponderous of evidence that *stable* composition keeping the crystalline "form" in a pharmaceutical composition must be supported by factual evidence:

> Muzaffar et al. p.60 "At any one temperature and pressure only one crystal form of a drug is stable and any other polymorph existing under these conditions will convert to the stable form .... " And p.63-65 (a)-(h) pharmaceutical preparing processes affect polymorphism;
>
> Jain et al. p.322-326, manufacturing processes that affect polymorphs ;
>
> Doelker et al. abstract, "One may also observe changes in technology or pharmaceutical properties that are due to polymorphic environmental conditions undergone by the product or the dosage form"
>
> Doelker et al. abstract "...a given drug, although chem. well defined, may exhibits quite different behavior. Process conditions (grinding, tableting, granulations, drying) may also affect secondary properties of the drug, such as compactibility, wetttability, soly, dissolution rate, bioavailability and even pharmacological, activity."

> Otsuke et al. p.852 ~ ...in formulation studies and the method preparing CBZ has been shown to affect the drug's pharmaceutical properties through the polymorphic phase transformation of the bulk CBZ powder during the manufacturing process"

Therefore, the state of the art evidenced that in possession of a crystalline pharmaceutical composition which maintains the crystalline form of the compound must be supported by physical measurement of such a composition with the desired crystalline characteristics being observed in the actual composition for which an operable carrier was included.

The amount of guidance and working examples

The specification, provided no composition for which an operable carrier would maintain stability of the crystalline forms. The specification provided no carrier, process or how such crystalline characteristics can be maintained in a stable environment as to be in possession of such a composition.

Applicants argued that there is not any reason to doubt that objective truth of the statements contained in the specification since the specification discloses that a pharmceutical composition comprising form I or form II of (S) citalopram oxalate and (S)citalopram oxalate may be formulate in a form suitable for oral administration or injection (specification at page 3).

Please note that the above per ponderous of evidence in the prior art clearly indicated that preparing a pharmaceutical composition "preserving" specific crystalline *form* does not happen automatically without guidance. The ordinary expectation using conventional carrier in the above per ponderous of evidence, is the *transformation* of crystalline form. Especially, applicant's argument that the *form* can be made in "injection" solution which is opposite to the scientific understanding of crystal, that is, in liquid all crystalline structure are abolished. The non-enabling and self contradiction nature as argued by attorney on p.4 of Jul.10, 2008 response is self evidenced.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boegesoe et al. US 4,943,590 or Christensen et al. US 6,916,941. In view of Cheronis supplemented with Sanches et al. US 6,960,613, US 6,768,011 or US 7,112,686 .

Determination of the scope and content of the prior art (MPEP §2141.01)

Boegesoe et al. '590, col. 6, lines 66-68, col. 10, claims 1 and 3 or Christensen et al. col. 5-6, examples 1-2. disclosed products prepared by identical processes which anticipated the claims (see section 3 supra).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art product is that the powdered X-ray diffraction pattern was included or a variation of solvent was employed in preparing the product. Cheronis taught that crystallization/recrystallization is a routine laboratory tool in purifying compounds. The employment of variation of common laboratory solvent would be an routine operation for such process (see p. 31-33). Sanches '613 taught that for the particular compound cyalopram oxalate, the same obvious routine recrystallization skill in purification is desirable (see col. 3, lines 30-35); Rock et al. '011 disclosed the employment of acetone for crystallization (see col. 6, line 1); Humble et al.(102(e) reference) taught that recrystallization of enantiomeric citalopram oxalate can employ alcohols, ketones, acetonitrile etc. (see col. 5, lines 22-25, col. 6, lines 8-11).

Finding of prima facie obviousness---rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art is well aware of all the pertinent art in the field. The above references provided the particular process to obtain the crystalline forms of s-citalopram oxalate with suggestions that further purification is desirable using routine recrystallization skill with common laboratory solvents. Further motivated by the operable solvents employed by analogous art, the particular choices among the common laboratory solvents are well delineated and suggested. In absent of unexpected results, the mere carrying out of routine purification or laboratory measurement of a known product is prima facie obvious **because** continuous purification of a pharmaceutical product is always a desirable modification of the known compound, especially, the selection of solvents are well delineated in the art. Further, the measurements of physical characterization of a purified product is the innate nature inseparable from the product per se absent of comparative and unexpected results.

The gist of applicants' argument is that *each* reference differed from the claims and there is no reasonable expectation of success when prior art processes were modified. Applicants

attention is drawn to that the all references recited in the rejection are analogous art. One skilled in the art is deemed to be aware of all the alternative choices of solvents for crystallization of (S)-citalopram oxalate. The motivation of obtaining purer, better crystals would have suggested to one skilled in the art to employ those alternative choices of solvents *explicitly* disclosed by Sanches, Rock or Humbel during crystallization of citalopram oxalate with the expectation that crystalline forms would be resulted. Such prima facie obviousness cannot be negated just because one gives the crystalline product obtained from alternative solvents a different name, a measurement of its physical properties. As it is well recognized by artisan in the field that "More than half of the pharmaceutical compds exhibits polymorphism…" (see Doelker CA138 supra) or "…in the strictest sense, polymophs are ….the same pure substance…" and patentability of new crystalline forms are normally granted on the basis of an advantage in terms of stability, formulation, solubility…..etc. (see Brittain p.2, 185). Further, in addition to the conventional teaching recited supra, the specific field of crystallization of citalopram salt has been well supplemented to the above references in the following factual evidence:

US 2002/0177722, p.7, example 7, disclosed crystallization of citalopram oxalate using acetone;

US 2004/0259940, p.6 example 4, disclosed crystallization of citalopram oxalate using ethanol;

US 2007/0117992, p.8, example 5, disclosed crystallization of citalopram oxalate using acetone;

US 2007/0129561, p.26, example 42, disclosed crystallization of citalopram oxalate using ethanol;

US 2008/0161584, p.8, last two paragraph, disclosed crystallization of citalopram oxalate using isopropanol.

US2005/0137255 p.4, example 1, disclosed how one having ordinary skill can use routine laboratory work as guided by Cheronis to carry out the process of picking and choosing appropriate solvent for crystallization of citalopram salt including ethyl acetate, methyl tert-butyl ether etc.

Therefore, both conventional and specific teaching would render the process of picking and choosing alternative operable solvent for crystallization of citalopram salt prima facie obvious to one having ordinary skill including those specific solvent limitations in the dependent claims.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Oct. 2, 2008

/Celia Chang/
Primary Examiner
Art Unit 1625